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HM11/0706

EXAMINER	
SCHWARTZMAN, R	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED:

07/06/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

# Office Action Summary

Application No.  
08/915,004

Applicant(s)  
Goto et al.

Examiner  
Robert Schwartzman

Group Art Unit  
1636



☒ Responsive to communication(s) filed on Apr 27, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-6, 10-14, 16, 19, 22, and 25 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☒ Claim(s) 1-3, 6, 10, 12-14, 16, 19, 22, and 25 is/are allowed.

☒ Claim(s) 4, 5, and 11 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

This Office action is in response to the amendment filed April 27, 1998. Claims 7-9, 15, 17, 18, 20, 21, 23, 24 and 26-31 have been canceled. Claims 1-6, 10-14, 16, 19, 22 and 25 are pending in this application.

#### ***Election/Restriction***

Applicant's election of Group I, claims 1-6, 10-14, 16, 19, 22 and 25 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). However, the restriction requirement is made moot by the cancellation of the non-elected claims in Paper No. 7.

#### ***Specification***

A substitute specification excluding claims is required pursuant to 37 CFR 1.125(a) because the amendment filed April 27, 1998 contains too many amendments to the specification to be entered by the Office.

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A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

Note that the amendments to the abstract and to the claims in the response filed April 27, 1998 have been entered. Further note that the objections to the specification regarding the Brief Description of the Drawing and sequence compliance made in the previous Office action mailed December 22, 1997 are still outstanding but would be obviated by the proposed amendments to the specification.

***Priority***

Acknowledgment is made of applicant's claim for benefit under 35 U.S.C. 120 to international application PCT/JP96/00374 filed February 20, 1996 and foreign priority based on applications filed in Japan on February 20, 1995 and July 21, 1995. It is noted, however, that

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applicant has not filed certified copies of these applications as required by 35 U.S.C. 119(b) and 365(c).

Applicants state that these priority documents were filed with the response on April 27, 1998 but such documents were not received by the Office.

### *Drawings*

Since allowable subject matter has been indicated, applicant is encouraged to submit formal drawings in response to this Office action. The early submission of formal drawings will permit the Office to review the drawings for acceptability and to resolve any informalities remaining therein before the application is passed to issue. This will avoid possible delays in the issue process.

Applicants state that formal drawings were filed with the response on April 27, 1998 but such drawings were not received by the Office.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is vague and indefinite as the recitation of percent identity is indefinite when the specification does not disclose how the calculation is made. Since there are numerous methods of determining identity between two sequences, particularly when it comes to gaps and other significant differences, disclosure of specific algorithms and parameters to be used is necessary to adequately define sequences meeting the claimed limitation.

Applicants argue that claim 11 was part of the application as originally filed and therefore does not require additional basis in the specification. Applicants further argue that there is no need for specific algorithms or parameters to calculate 80% sequence identity and that the skilled artisan would interpret 80% sequence identity to define proteins that share 4 out of 5 amino acids

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with the reference protein, where 1/5 or 20% of the amino acids are different. These arguments have been fully considered but are not deemed to be persuasive. Although the term "80% sequence identity" was part of the specification as originally filed, the specification fails to teach how to calculate percent sequence identity. It is not as simple as suggested by applicants' arguments. Sequence comparison algorithms, of which many exist, use different calculation methods and thus provide different answers for the percent identity between two sequences. Even with the same algorithm, the various parameters that are set prior to the calculation, such as joining penalties, gap penalties and gap size penalties, have a tremendous influence on the answer provided by the algorithm. First, it is not straightforward to align two sequences, particularly when they are of different lengths, and multiple alignments will almost always be possible. Second, the alignment makes a big difference in the calculation of percent identity as a gap of the length of 20% of the amino acids at the end of the sequence will be different from a gap of the same length in the middle of the sequence which will be different from 10 gaps which total 20% of the amino acids and each of these situations will give different answers depending on the penalties set in the algorithm. Thus, a definition of the algorithm and parameters to be used to make the sequence comparison is critical to determining which sequences are encompassed by the metes and bounds of the claim.

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*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 4 and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by Tsuda et al.

Tsuda et al. teaches (entire document) an osteoclastogenesis inhibitory factor protein purified from human fibroblasts cultured on alumina ceramic pieces. The protein was purified by ion-exchange, affinity and reverse phase chromatography.

Applicants argue that Tsuda et al. is not available as prior art as it was published after the priority date of the present application. This argument is not deemed to be persuasive as applicants have not perfected the claim to priority under 35 U.S.C. 119 and 120. Until such time as the priority claim is perfected Tsuda et al. remains as prior art.



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***Conclusion***

Claims 4, 5 and 11 remain rejected. Claims 1-3, 6, 10, 12-14, 16, 19, 22 and 25 are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

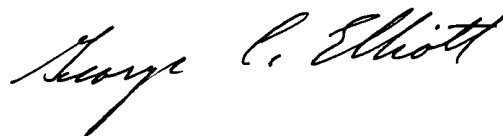
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Schwartzman whose telephone number is (703) 308-7307. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached at (703) 308-4003. The fax number for this group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)-308-0196.

Robert A. Schwartzman, Ph.D.  
June 30, 1998

A handwritten signature in cursive script, reading "George C. Elliott".

George C. Elliott, Ph.D.  
Supervisory Patent Examiner  
Technology Center 1600